

### REMARKS

The present document is submitted in reply to the Office Action dated November 14, 2007 ("Office Action").

Applicant has amended claims 1, 3, and 4, support for which appears at various places in the specification, e.g., page 3, lines 13-19; and page 31, lines 10-13. Further, Applicant has amended claims 5-11, originally independent, such that they now depend from claim 1; amended claims 17 and 18 such that they now include all of the limitations of amended claim 1; amended claims 12-14, 19, and 20 to promote clarity; and amended claim 23 to correct a typographical error. In addition, Applicant has added and withdrawn new claim 29, support for which can be found in original claim 4, and cancelled claims 2 and 16. Finally, Applicant has amended the specification at page 20 to correct a typographical error. No new matter has been introduced.

Upon entry of the present amendments, claims 1, 3, 4, 7, 10-13, and 18-20 will be under examination.<sup>1</sup>

Applicant respectfully requests that the Examiner reconsider this application in view of the following remarks.

#### Defective Declaration

Applicant acknowledges the remarks with regard to the Declaration (see the Office Action, at page 2, section 2) and will file a re-executed Declaration accordingly as soon as it becomes available.

#### Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1-4, 7, 10-13, and 18-20 are rejected for indefiniteness on five grounds (see the Office Action, at pages 3-4, section 3), which will be addressed below separately.

First, according to the Examiner, the recited term "immunomodulator" is vague as it "could be interpreted in a variety of ways." See the Office Action, page 3, section 3A. Applicant disagrees. Nonetheless, for the sole purpose of expediting prosecution,

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<sup>1</sup> Among the other pending claims, claims 5, 6, 8, 9, 14, 15, 17, 18, and 21-28 were withdrawn from consideration previously and claim 29 will be withdrawn from consideration.

Applicant has replaced the term “immunomodulator” with “construct,” thus obviating the rejection.

Second, the Examiner states that the term “fully functional,” “little or no ability,” and “defective T cell receptor binding site,” recited in previously presented claim 1, 2, or 7, are indefinite. See the Office Action, page 3, section 3B. Applicant has deleted these terms, thereby rendering the rejection moot.

Third, the Examiner holds that the term “one or more mutations at positions 18, 42, 75, and 182 in SEQ ID NO:1” recited in claims 3 and 19 is vague on the ground that “it is unclear how a single amino acid can comprise multiple mutations.” See the Office Action, pages 3-4, section 3C. Applicant has replaced this term with “a mutation at one or more positions of 18, 42, 75, and 182 of SEQ ID NO:1,” now recited in amended claims 1 and 18, to clarify that one or more mutations can be introduced into SEQ ID NO:1, each at position 18, 42, 75, or 182. It is submitted that this amendment has overcome the rejection.

Fourth, the Examiner points out that the term “the defective TCR binding SMEZ-2” recited in claim 7 has insufficient antecedent basis. See the Office Action, page 4, section 3D. This term has been removed.

Finally, claim 19 is held as indefinite on the ground that “[i]t is unclear whether the claim[] [is] intended to encompass superantigen with the sequence of SEQ ID NO:1 or any protein designated “SEQ ID NO:1.” See the Office Action, page 4, section 3E. Applicant has amended claim 19 to clarify that this claim is directed to a superantigen having the amino acid sequence of SEQ ID NO:1 with one or more mutations at defined residue positions. Claim 19, as amended, is believed to be definite.

Rejection under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 1, 2, 7, 10-13, and 18 are rejected for lack of written description. More specifically, the Examiner deems these claims as overly board, i.e., encompassing any antigen-presenting-cell (APC) targeting molecule that mimics SMEZ-2 or that is structurally a SMEZ-2. See the Office Action, page 4, fifth paragraph. Applicant has cancelled claim 2.

The standard for the written description requirement under 35 U.S.C. § 112, first paragraph, is set forth in *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). “If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, ... then the adequate description requirement is met.” See also MPEP 2163.

In the present case, Applicant has narrowed independent claim 1 to limit it to “a mutant of superantigen SMEZ-2 containing a mutation at one or more positions of 18, 42, 75, and 182 in SEQ ID NO:1.” Claim 1, as amended, covers a construct containing an antigen coupled with an APC-targeting molecule that includes the SMEZ-2 mutant described above. As correctly pointed out by the Examiner, the present specification discloses the SMEZ-2 mutant recited in amended claim 1, i.e., “the SMEZ-2 polypeptide of SEQ ID NO:1 with mutations at residues 18, 42, 75, and/or 182”. See the Office Action, page 5, first paragraph. Accordingly, a skilled person in the art would have no doubt that Applicant was in possession of the recited SMEZ-2 mutant at the time this application was filed. He or she would also readily know that Applicant was in possession of the construct of claim 1, which contains the just-mentioned SMEZ-2 mutant. Pursuant to the legal standard quoted above, amended claim 1 satisfies the written description requirement.

Among the other rejected claims, claims 7 and 10-13 depend from claim 1, and claim 18 (a product-by-process claim), as amended, covers a family of constructs having the same scope as that covered by claim 1 (a product claim). Thus, for at least the same reason, these claims also meet the written description requirement.

#### Rejection under 35 U.S.C. § 103

Claims 1-4, 7, 10-13, and 18-20 are rejected as obvious over WO 0245739 (“WO ’739”) in view of Park et al., (“Park”). See the Office Action, pages 5-6, section 5. Note that claim 2 has been cancelled.

Applicant would like to point out that WO ’739 is not a qualified prior art reference against the present application for the following reasons.

It is well settled that “[a] 35 U.S.C. 103 rejection is based on 35 U.S.C. 102(a), 102(b), 102(e), etc. depending on the type of prior art reference and its publication or issue date.” See the MPEP § 2141.01(I). Further, “[s]ubject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of the section 102 of this title [35 U.S.C.], shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.” See 35 U.S.C. 103(c).

In this case, as WO '739 is a published PCT application, 35 U.S.C. 102(a), 102(b), and 102(e) are the only pertinent provisions of 35 U.S.C. 102 for determining whether this reference is citable. WO '739 was published on June 13, 2002, later than the priority date of the present application, i.e., June 4, 2002. Thus, this reference is not citable under 35 U.S.C. 102(a) and 102(b), both requiring that a qualified prior art reference must be published earlier than when the invention was made.<sup>2</sup> Further, the invention named in the present application, i.e., John David Fraser, is also named as an inventor in WO '739. Applicant submits that WO '739 actually discloses the inventor's own work. Accordingly, this reference is not citable under 35 U.S.C. 102(e), which requires that a qualified prior art patent application must be filed by “another.”

Even if WO '739 qualifies as a 102(e) reference (which Applicant does not concede), pursuant to 35 U.S.C. 103(c) quoted above, this reference is still not citable for an obviousness rejection. 35 U.S.C. 103(c) disqualifies a 102(e) reference, if the subject matter disclosed therein and the claimed invention were owned by the same person at the time the invention was made. Here, both WO '739 and the present application were commonly owned by Auckland Uniservices Limited.<sup>3</sup> In other words, the subject matter disclosed in WO '739 and the invention claimed in the present application were owned

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<sup>2</sup> To simply discussion, Applicant assumes that the invention claimed in the present application was made at the priority date of this application. However, by doing so, Applicant does not concede that the invention was made no earlier than the priority date.

<sup>3</sup> The cover pages of WO '739 and WO 03/101173, on which the present application is based, all indicate that Auckland Uniservices Limited is the owner of both PCT applications.

by the same person. In accordance with 35 U.S.C. 103(c), this reference does not qualify as a prior art reference to support an obviousness rejection in the present application.

In view of the above remarks, Applicant submits that it is improper to rely on WO '739 to reject any claims in this application for obviousness.

As correctly pointed out by the Examiner, the remaining cited reference, i.e., Park, teaches that "ovalbumin is a well characterized model antigen comprising defined epitopes that is useful for studying the immune response to vaccination." See the Office Action, page 6, third paragraph. Clearly, this reference is irrelevant to a construct containing a mutated superantigen SMEZ-2 coupled with an antigen (e.g., ovalbumin), the subject matter of rejected claims 1, 3, 4, 7, 10-13, and 18-20. Thus, Park alone does not render these claims obvious.

For the reasons set forth above, Applicant respectfully requests that the Examiner withdraw this rejection.

#### CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment.

In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed.

Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

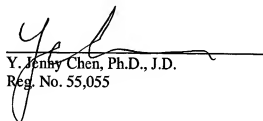
Applicant(s) : John David Fraser  
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The Petition for Extension of Time fee in the amount of \$ 460 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges to Deposit Account No. 50-4189, referencing Attorney Docket No. 55502-007US1.

Respectfully submitted,

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